K040936

MAY - 3 2004

APPENDIX E

510(k) SUMMARY
Petit Silma Elastic Bandage
Bio-Lipid, Inc.

This 510(k) summary of safety and effectiveness for Petit Silma Elastic Bandage is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Bio-Lipid, Inc.
Address:	7000 SW 97 Avenue Suite 213 Miami, FL 33173
Contact Person:	David J. Bloch Regulatory Counsel
Telephone:	(202) 414-9209 (telephone) (202) 414-9209 (fax)
Preparation Date:	March 2004
Device Trade Name:	Petit Silma Elastic Bandage With Germanium/Titanium Oxide
Common Name:	Elastic Bandage or Compression Bandage
Classification Name:	Elastic Bandage (see 21 C.F.R. § 880.5075) Product Code: FQM
Predicate Devices:	Comfort Care™ Compression Support With Magnets, 510(k) # K013239, manufactured by Med Gen, Inc.
Device Description:	The Petit Silma Elastic Bandage is a simple device to provide relief of minor physical discomforts arising from stress or strain of repetitive actions including athletic, workplace and at-home activities. It consists of an elastic compression bandage, containing the element Germanium in a circular pellet. The product is worn on the injured portion of the body (elbow, knee, wrist) as appropriate. Alternatively, a second version of the the product would contain a Titanium Oxide pellet, instead of Germanium.

Intended Use:	Petit Silma Elastic Bandage is an elastic bandage to provide relief of minor physicial discomforts that have their origin in stress and strain of repetitive actions associated with athletic, workplace and at-home activities. The device provides support for unprotected vulnerable body parts and post-injury impact induced by overexertion in self-limiting physical injuries.
CONCLUSIONS:	Based on the foregoing and other information in this application, Bio-Lipid, Inc. believes that the Petit Silma Elastic Bandage is substantially equivalent to its claimed predicates under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2004

Leda Company Limited
C/O Mr. David J. Bloch
Regulatory Counsel
Reed Smith, L.L.P.
1301 K Street, N.W. Suite 1100-East Tower
Washington, D.C. 20005-3373

Re: K040936
Trade/Device Name: Petit Selma Elastic Bandage with Germanium/Titanium Oxide
Regulation Number: 880.5075
Regulation Name: Elastic Bandage
Regulatory Class: I
Product Code: FQM
Dated: April 9, 2004
Received: April 9, 2004

Dear Mr. Bloch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

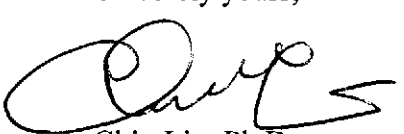
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040936

Indications for Use

510(k) Number (if known): K040936

Device Name: Petit Selma Elastic Bandage with Germanium/Titanium Oxide

Indications For Use:

The Petit Silma Elastic Bandage with Germanium/Titanium Oxide is designed to provide relief of minor physicial discomforts that have their origin in stress and strain of repetitive actions associated with athletic, workplace and at-home activities. The device provides support for unprotected vulnerable body parts and post-injury impact induced by overexertion in self-limiting physical injuries.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Irene Nanassa for ADW 4/29/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040936